

REMARKS

Currently, claims 1, 3-6, 8-13, 15-19, 21, 23 and 24 are pending in the application. Claims 3 and 4 are currently amended to correct dependency

I. APPLICANTS' INVENTION

The present invention relates to a removable device such as a stent-graft, intended for applications where it may be desirable to remove the device at some time following implantation. The stent-graft includes a helically-wound stent component provided with a covering of graft material having anisotropic strength properties. It is removable by gripping an end of the helically-wound stent component with a retrieval device and applying tension to the stent component in the direction in which it is intended to be withdrawn from the site of implantation. The use of such a retrieval device allows the stent-graft to be removed remotely, such as via a catheter inserted into the body at a different location from the implantation site. The design of the stent-graft is such that the stent component is extended axially while the adjacent portion of the graft separates between windings of the stent component. The axial extension of the stent component, with portions of the graft still joined to the stent component, allows the device to be "unraveled" (or "unwound") and removed through a catheter of diameter adequately small to be inserted into the body cavity that contained the stent-graft. It is removed atraumatically, without incurring significant trauma to the body conduit in which it had been deployed.

II. REJECTION OF CLAIMS 23 AND 24 UNDER 35 USC 112, FIRST PARAGRAPH AS FAILING TO COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT.

The Examiner states that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention. The Examiner referenced the specification text at page 11, lines -18 relating to Figure 4C, all of which describes the anisotropic strength properties of the graft material.

Claims 23 and 24 depend from claim 1, which requires that the graft material has anisotropic strength properties and is oriented so as to be weaker in the longitudinal direction than in the circumferential direction (thereby allowing the graft material to split in

the circumferential direction when a suitable longitudinally-oriented force is applied).

Claim 23 adds the requirement that the graft material is provided with a row of perforations extending through at least a portion of the graft thickness; claim 24 adds the requirement that the graft material is provided with a line of reduced thickness in comparison to the thickness of the remainder of the graft material.

The use of perforations as a means for splitting of the graft material, and the use of thinner material for the same purpose, is described at page 10, lines 30-36 and by Figure 4B (in addition to claims 23 and 24 as originally filed). While these are taught as various means for splitting, the specification does not require that each of the described means must be used exclusively. Applicants are unaware of any requirement that precludes claiming any of the variously taught means in any combination. As such, claims 23 and 24 are not in violation of 35 USC 112, first paragraph.

III. REJECTION OF CLAIMS 3 AND 4 UNDER 35 USC 112, SECOND PARAGRAPH AS FAILING TO PARTICULARLY POINT OUT AND DISTINCTLY CLAIM THE SUBJECT MATTER WHICH APPLICANT REGARDS AS THE INVENTION.

The Examiner pointed out that these claims depended from a now-canceled claim. Claims 3 and 4 are currently amended to correct their dependency.

IV. REJECTION OF CLAIMS 1, 3-6, 8-13, 15-19 and 21 UNDER 35 USC 102(b) AS ANTICIPATED BY SMITH, US PATENT 6,364,904.

The Examiner concludes that Smith teaches all of the elements of the 102(b)-rejected present claims. Smith teaches a stent-graft that is made from a helically wound strip of material (preferably ePTFE) that is adhered to a length of serpentine, helically wound wire. For ePTFE, it is noted that that material can be made by uniaxial, biaxial or multiaxial stretching. While the uniaxial and biaxially stretched ePTFE materials can have anisotropic strength properties, any orientation of these materials with regard to the stent-graft assembly is not taught; indeed, none of these material choices is stated to be preferred.

The strip/wire composite is helically wound to create a tubular structure. For most embodiments described, the adjacent edges of the helically wound strip are sealed together to create a fluid tight tubular prosthesis. Alternative embodiments are described

wherein the adjacent edges of the helically wound wire and strip are not sealed, but are rather left spaced apart with the result that those embodiments are not intended to be fluid tight (see, for example, Figures 14, 18 and 21).

Only the fluid tight embodiments relate to the present rejection. For each of these, Smith particularly points out that the adjacent edges of the strip and wire composite are sealed together. Applicants contend that the sealed edges of Smith, which are always shown to be overlapping edges that double the material thickness, clearly teach away from a prosthesis that is splittable (for removability from the vasculature in which it was previously implanted) by virtue of constructing the graft material from a material having anisotropic strength properties. The sealing of the adjacent edges would inevitably result in increasing the strength of the graft material and render it more resistant to splitting. The necessity of sealing these edges to create a fluid tight prosthetic is emphasized repeatedly; see col. 5, lines 4-7 and lines 19-26; col. 6, lines 32-41 and 62-64; col. 7, lines 25-28, 34-37 and 60-62; col. 8, lines 46-49 and 60-62; and col. 8, line 67 to col. 9, line 3. Clearly, for the person of ordinary skill, the sealed and overlapped edges of Smith that are necessary for his fluid tight prosthesis are not in any way suggestive of a splittable construction.

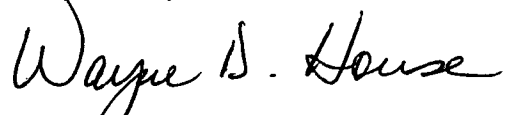
Further, Smith never suggests removability of his devices; the concept of removability is never addressed.

There is simply no suggestion to the person of ordinary skill that his devices might be splittable by the use of an anisotropic material. Accordingly, the present claims are not anticipated by Smith.

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance. If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully Submitted,

A handwritten signature in black ink that reads "Wayne D. House". The signature is written in a cursive style with a large, looping "W" and a distinct "H".

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